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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,950	03/20/2002	Frederic J de Sauvage	11669.0123USWO	4737

23552 7590 03/06/2007
MERCHANT & GOULD PC
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EXAMINER	
GAMETT, DANIEL C	

ART UNIT	PAPER NUMBER
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/088,950	DE SAUVAGE ET AL.	
	Examiner	Art Unit	
	Daniel C. Gamett, PhD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,20,23-25 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17, 20, 23-25, and 35* is/are rejected.

7)☒ Claim(s) *25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/2006 has been entered.

2. The amendments of 12/21/2006 have been entered in full. Claims 1-16, 18, 19, and 26-34 are cancelled. Claims 17, 20, 23-25, and 35 are under examination.

3. All prior objection/rejections not specifically maintained in this office action are hereby withdrawn.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Claim Objections

5. Claim 25 is objected to because of the following informalities: The term F(ab)' should be F(ab)'2 or F(ab)'$_2$. The number '2' is missing. Appropriate correction is required.

Rejections Maintained

Double Patenting

6. The provisional obviousness-type double patenting rejection of Claims 17, 20, and 23-25 being unpatentable over claims 15-18, 20, and 23-25 of copending Application No. 10/663158,

set forth in the office action of 12/07/2005, will be maintained until such time as it becomes the only rejection remaining in this application.

Claim Rejections - 35 USC § 112

7. Claims 17, 20, 23-25, and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claim 17 is drawn to a method of treating an allergic disorder in a mammal comprising administering to said mammal a therapeutically effective amount of a TCCR agonist antibody or TCCR binding fragment thereof. Claims 23 and 24 recite antibody fragments, and claim 25 adds the limitation wherein the agonist antibody or fragment is a single-chain antibody, linear antibody, Fab, Fab', $F(ab)'_2$, Fv, or diabody. The fact that a patent is directed to method entailing use of a compound, rather than to the compound *per se*, does not remove patentee's obligation to provide description of the compound sufficient to distinguish infringing methods from noninfringing methods (University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CAFC 2004)). In this case, the claims are drawn to methods that comprise administration of a genus of compounds recited as TCCR agonist antibody, TCCR binding fragment thereof, antibody fragments, a single-chain antibody, linear antibody, Fab, Fab', $F(ab)'_2$, Fv, or diabody. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be

considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, it is evident that, given the amino acid sequence of TCCR, a person of skill in the art at the time of filing would reasonably be expected to be able to make anti-TCCR antibodies and fragments thereof. However, the agent required by the claimed method must have the activity of being an agonist of TCCR. A fragment that merely retains capability to bind TCCR and/or only retains one antigen binding domain (such as Fab, Fab', or Fv) and activates TCCR is not described in the instant specification. Furthermore, such a fragment is not known, or even expected, in the art. Intact antibodies, and fragments that retain at least two antigen binding domains, can act as agonists of cytokine receptors by crosslinking receptor molecules. Known agonist antibodies, and the strategies for their development, take into account the requirement to simultaneously bind at least to receptor molecules or subunits (see U.S. Patent Application Publication 20050164307 at [0002]-[0004]). The record shows that the prior art teaches the existence of an agonist antibody for TCCR. However, even with this information, the skilled artisan skilled artisan cannot envision the detailed chemical structure of the encompassed fragments, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

8. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

9. Claims 17, 20, 23-25, and 35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating an allergic disorder in a mammal comprising administering to said mammal a therapeutically effective amount of a TCCR agonist antibody or bivalent fragments thereof which retain agonist activity, does not reasonably provide enablement for any method of treatment comprising administration of a monovalent antibody fragment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. In view of Applicant's arguments and references submitted on 12/21/2006, it appears that the prophetic teachings of the instant specification regarding the ability of TCCR agonist antibodies to bring about immune deviation have been substantiated. This scope of enablement cannot, however, be extended to include methods that employ monovalent antibody fragments, or fragments that are merely described as "TCCR binding". The prior art teaches that known cytokine receptor agonist antibodies are capable of simultaneously binding at least to receptor molecules or subunits, and that strategies for the development of agonist antibodies take this requirement into account (see U.S. Patent Application Publication 20050164307 at [0002]-

[0004]). Intact antibodies, and fragments that retain at least two antigen binding domains, can act as agonists of cytokine receptors by crosslinking receptor molecules. An antibody fragment that merely retains capability to bind TCCR and/or only retains one antigen binding domain (such as Fab, Fab', or Fv) and activates TCCR is not known in the art and it is not clear that such a fragment is even possible. Therefore, development of a method that requires use of such a fragment would require undue experimentation on the part of the skilled artisan.

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DCG
Art Unit 1647
27 February 2007

David Romeo
DAVID S. ROMEO
PRIMARY EXAMINER